

REMARKS

The Office Action mailed April 14, 2006, and the new prior art relied upon therein have been carefully studied. The claims in the application are now claims 1-6, 8, 9, 11-20, 22, 23 and 25-30, and these claims define novel and unobvious subject matter under §§102 and 103, and therefore should be allowed. Favorable consideration and allowance are therefore earnestly solicited.

Acknowledgement by the PTO of the receipt of applicant's papers filed under Section 119 is noted.

Applicant's formulation comprises three distinct layers on top of the core, and these three layers must differ from one another:

1. A layer of Venlafaxine Hydrochloride, which is coated on a nonpareil inert core with water soluble binder.
2. A layer of water-soluble polymer (which may be or may be not the same polymer as the binder). This isolating/protecting/separating layer (sub-coating) is essential because the Venlafaxine Hydrochloride tends to influence the stability of the outer coating and should be separated by this layer.

3. A layer of hydrophobic polymer mixed with an appropriate hydrophobic or hydrophilic plasticizer (outer coating). This (outer) layer enables the controlled release of venlafaxine hydrochloride.

Claims 1, 3, 4, 19 and 24-26 have been rejected as anticipated by Jeary et al WO 00/71099. The rejection is respectfully traversed.

Nevertheless, as the features of claims 7 and 21 have been incorporated into claim 1. As neither claim 7 nor claim 21 was so rejected, applicant need not further address this rejection at the present time.

However, and for the record, the amendments are made without prejudice to applicant's rights to pursue broader claims in a continuing application at a later time, if applicant so wishes to do so, without any penalty whatsoever, and with applicant relying on §§119 and 120.

Claims 1-30 have been rejected as obvious under §103 from Jeary in view of McTeigue et al USP 6,149,943 (McTeigue) and Kamada USP 5,505,983 (Kamada). This rejection is respectfully traversed.

Jeary teaches an extended release formulation comprising an active ingredient and a binder coated on a sugar nonpareil inert core, which enables the controlled release of

the active material over an extended time period. The coating system described in the present invention is importantly different in its composition and functionality.

The PTO appears to misinterpret the disclosure by Jeary of a polymeric layer composed of Eudragit and a plasticizer (pg. 8, lines 6-17 and pg. 9, lines 16-22) as an additional polymeric layer. Please note the description of the layers comprising said formulation on pg. 8, line 6-17 of Jeary where Jeary explicitly mentions (pg. 8, line 16-17) that "the core can comprise layers of said powder mixture and said polymeric material superimposed one upon the other". In other words, there is no additional and different polymeric layer, but instead an alternation of the layers of the powder mixture and polymeric material comprising said formulation.

Hence, there is only in effect one layer of coating on the powder of the active ingredient in Jeary.

On the other hand, the present invention relates to an extended release composition comprising as active compound venlafaxine hydrochloride, in which venlafaxine hydrochloride is coated on a nonpareil inert core with water soluble binder, which coated core is coated with a water-soluble polymeric layer (which may be or may be not the same polymer as the binder). Such sub-coating is very important since the

venlafaxine hydrochloride tends to influence the stability of the coating and should be separated by sub-coating.

The core or the isolating layer is coated then with an additional polymeric layer which enables the controlled release of venlafaxine hydrochloride. Such additional polymeric layer is composed of a hydrophobic polymer mixed with an appropriate hydrophobic or hydrophilic plasticizer. In contrast to Jeary, the present invention involves a formulation having a coating of an active ingredient core with two adjacent polymeric layers, one of which is water-soluble and another which is water-insoluble. Thus, Jeary does not anticipate or maybe obvious the presently claimed invention.

Further, the active materials including venlafaxine hydrochloride listed in said referenced document strongly vary in their solubility, which essentially affects the choice of polymer. This particular choice is not trivial because of the choice of coating is dependent on the solubility on the active ingredient.

In respect to McTeigue's disclosure of microcrystalline cellulose based pellets, which are suitable for compression into tablets, attention is invited to the foregoing arguments. McTeigue has a very broad disclosure; however the venlafaxine hydrochloride is not claimed. McTeigue exemplifies only the water-insoluble active

ingredients. It is not obvious for any person skilled in the art that the water-soluble venlafaxine hydrochloride would be controllably released from the system disclosed by McTeigue because, as we have already said above, the solubility of the venlafaxine chloride strongly affects the rate of release; and as a result, the choice of coating.

Finally, Kamada describes the rotor process and coating seeds in a rotor system, which has nothing to do with rate controlling of highly soluble materials like the venlafaxine hydrochloride. Based on Kamada's teaching, it is not trivial for a skilled artisan to prepare formulation suitable for the controlled release of the venlafaxine hydrochloride. Furthermore, the choice of coating is not trivial and cannot be taught from said patent. The coating suitable for water-insoluble active material is not always suitable for the water-soluble material. The references would not have been obviously combined, as there is no reason or purpose, motive or incentive for the proposed combination. Moreover, even if the combination were obvious (contrary to applicant's position), the resultant reconstruction of Jeary in view of McTeigue and Kamada would not reach the claimed subject matter.

Withdrawal of the rejection is in order and is respectfully requested.

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Reply to Office Action of April 14, 2006

The prior art documents of record and not relied upon by the PTO have been noted, along with the implication that such documents are deemed by the PTO to be insufficiently material to warrant their application against any of applicant's claims.

Applicant believes that all issues raised in the Office Action have been addressed above in a manner favorable to allowance of the present application. Accordingly, applicant respectfully requests favorable reconsideration and early formal allowance.

Respectfully submitted,

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